

## REMARKS

In the above referenced office action, the claims were rejected under 35 USC 103 over Christopher either alone or in combination with various references. Applicant respectfully traverses.

As amended, claim 1 recites an oblong member configured to open a urethral sphincter and drain fluid from the bladder into the urethra; thus, defining the structural requirements of the oblong member accordingly. In other words, the oblong member opens the sphincter, allows fluid flow around or through it into the urethra, and relies upon the urethra to direct fluid flow once past the urethral sphincter. In addition, claim 1 has been amended to recite that the guide member is fixedly attached to the oblong member. As this is an intermittent catheter intended for one time use, the patient navigates the oblong member to the urethral sphincter using the guide member. The oblong member is then pushed through the sphincter (partially) to open and hold open the sphincter. Urine then passes by or through the oblong member (as it holds open the sphincter) into the urethra where it is voided. The guide member remains in place during voiding. Upon completion, the guide member is retracted and removed, thereby removing the oblong member as well and permitting the sphincter to close.

Christopher fails to teach an oblong member configured to open the urethral sphincter and drain fluid from the bladder into the urethra and also fails to teach a guide member that is fixedly coupled to anything, let alone to such an oblong member. Christopher teaches an indwelling catheter that includes a retaining head 40 that is inserted into the bladder and expanded so as to retain the catheter in position for an extended period of time. A rigid portion (14) of the catheter does maintain the sphincter in an open position; however, fluid flow is directed from the head and into a tubular body and is not introduced into the urethra. Thus, for at least the reasons that Christopher fails to teach or suggest the oblong member as claimed as well as the guide member fixedly coupled with such a member, the rejection is unsupportable and must be withdrawn.

Claim 21 has been added and includes an oblong member, similarly configured to open the urethral sphincter and drain fluid from the bladder, but also includes a recitation that the

oblong member is solid and has an external channel positioned on an exterior. The dependency of claims 9-12 has been amended such that they depend from new claim 21.

The Examiner previously rejected claim 14 over Christopher in view of Tihon, asserting that Tihon teaches a solid member. Tihon fails to teach an oblong member at a distal end of the device configured to open a urethral sphincter. In fact, Tihon is specifically provides an embodiment with a narrowed segment (32) that permits the sphincter to close and seal around the device and preclude urine flow (as this is also an longer term catheter). Further, the Tihon device includes a shaped coil (22) that is inserted through the sphincter and into the bladder. Thus, this provides for a structurally different device than presently claimed, wherein the distal end of the device is used to open the sphincter and does not have a component that extends significantly into the bladder, thereby avoiding irritation, damage, or the like.

Tihon also fails to teach a guide member fixedly coupled with the oblong member as claimed. That is, Tihon explicitly requires a wire stylet (that is not illustrated, Col 3, line 61) in or order to facilitate insertion. As this is also an indwelling catheter intended for longer term use, the incorporation of a guide member that is fixedly coupled to the device yet includes the claimed elastically deformable material property is neither taught nor suggested and would be contrary to the explicit teachings of the reference.

None of the other references cited, alone or in combination address the deficiencies noted above. As such, Applicant respectfully asserts that the references fail to teach or suggest the presently pending claims.

Applicants : Tanghoej  
Serial No. : 10/539,777  
Filed : 20 June 2005  
Page : 7 of 7

Attorney Docket No.: 2002002-US

## **CONCLUSION**

Applicant respectfully asserts that the pending claims are in condition for allowance and notice of the same is respectfully requested. Should any issues remain outstanding, the Examiner is respectfully urged to telephone the undersigned. No additional fee are believed due at this time; however, the office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4429.

Respectfully submitted,  
Tanghoej

Date: 13 Feb 2009

/Daniel G. Chapik  
Daniel G. Chapik, Reg. No. 43,424  
Director and Chief Patent Counsel  
Coloplast Corp., Coloplast A/S  
Customer No. 69289  
Telephone: (612) 344-2376